UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT LITIGATION) MDL No. 04-1592

MEMORANDUM AND ORDER

WOLF, D.J. November 5, 2004

I. SUMMARY

The Trustees of the Columbia University in the City of New York ("Columbia") have moved to dismiss the declaratory judgment claims in these multidistrict litigation cases. Columbia alleges that its covenant not to sue the plaintiff drug companies on the claims of Patent No. 6,455,275 (the "'275 patent") as they now read extinguishes the constitutionally required actual cases or controversies between the parties with regard to plaintiffs' requests for declaratory judgment. Plaintiffs oppose this motion.

For the reasons set forth in this Memorandum, however, Columbia's contention is correct. The covenant not to sue means that none of the plaintiffs now has the legally required reasonable apprehension that it will face an infringement suit if the court does not declare the '275 patent invalid and/or unenforceable. Moreover, the court has some discretion as to whether to exercise its jurisdiction even where an actual case or controversy exists. In the circumstances of these cases, even if contrary to the court's conclusion subject matter jurisdiction now exists, it would be most appropriate to dismiss the requests for declaratory judgment rather than devote a substantial amount of scarce judicial

resources to rendering an essentially advisory opinion on hypothetical facts concerning contingencies that are not likely to occur.

Therefore, plaintiffs' requests for judgment will be dismissed. In addition, the parties are being ordered to: confer; identify for the court the remaining issues in this multidistrict litigation; inform the court whether they request an opportunity to attempt to settle the remaining issues; and, if not, propose a schedule for their judicial resolution.

II. FACTS

The plaintiffs are drug companies which have licensed from Columbia all patents deriving from an application that Columbia filed in 1980 (the "Axel Patents"). Plaintiffs believed that the last of the licensed Axel Patents that they were practicing expired in 2000 and that their duties to pay royalties to Columbia ended in 2002. However, plaintiffs were informed by Columbia that a new patent deriving from the 1980 application, the '275 patent, had been issued on September 24, 2002. Columbia asserted that plaintiffs were, therefore, obligated to pay royalties for another seventeen years.

Plaintiffs contend that the '275 patent is invalid pursuant to the doctrine of non-statutory double patenting and for other reasons. They also assert that, if valid, the '275 patent is

unenforceable because of prosecution laches. Therefore, plaintiffs ceased paying royalties to Columbia under their respective licensing agreements.

In 2003, various plaintiffs filed suits against Columbia, in various United States District Courts, seeking declaratory judgments that the '275 patent is both invalid and unenforceable.[1] Some of the plaintiffs also seek other relief, but the requests for declaratory judgment are the heart of each of the actions.

In 2004, Columbia notified each plaintiff that it was

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[1]Genentech, Inc. ("Genentech") filed the first action on April 15, 2003 in the Northern District of California (C.A. No. 04-11546). Immunex Corporation ("Immunex") and Amgen, Inc. ("Amgen") filed their suit on June 18, 2003 in the Central District of California (C.A. No. 04-10740). Biogen, Inc. (now known as "Biogen Idec MA"), Genzyme Corporation ("Genzyme") and Abbott Bioresearch Center, Inc. ("Abbott") filed suit on July 15, 2003 in the District of Massachusetts (C.A. No. 03-11329). Wyeth and Genetics Institute, LLC ("Genetics Institute") filed suit on August 20, 2003 in the District of Massachusetts (C.A. No. 03-11570). Baxter Healthcare Corporation ("Baxter") filed suit on November 12, 2003 in the District of Massachusetts (C.A. No. 03-12221). Serono, Inc. ("Serono") and Ares Trading S.A. ("Ares") filed suit on November 26, 2003 in the District of Massachusetts (C.A. No. 03-12401).

On October 31, 2003, Columbia sued Johnson & Johnson and Ares in the Northern District of California (C.A. No. 04-10742). Johnson & Johnson sued Columbia on November 11, 2003 in the Southern District of New York (C.A. No. 04-10743).

Some of these cases have been resolved. On May 26, 2004, the court entered stipulated orders of dismissal in the cases involving Serono and Ares (C.A. No. 03-12401) and Baxter (C.A. No. 03-12221).

On June 15, 2004, the parties filed a stipulation of dismissal of Columbia's case against Johnson & Johnson (C.A. No. 04-10742) to permit Columbia's claims to be asserted as counterclaims in the other case between Columbia and Johnson & Johnson (C.A. No. 04-10743).

terminating its license as a result of its refusal to pay royalties on the '275 patent. Two of the plaintiffs, Biogen Idec MA and Genzyme, filed a motion to preliminarily enjoin the termination of their licenses.

On April 8, 2004, the Judicial Panel on Multidistrict Litigation transferred all of the cases relating to the '275 patent to this court for coordinated or consolidated pretrial proceedings.

After a hearing on June 22, 2004, this court denied Biogen Idec MA and Genzyme's motion for preliminary injunction. See Biogen Idec MA Inc. v. The Trustees of Columbia University in the City of New York, 332 F.Supp.2d 286 (D. Mass. 2004). In reaching that decision, the court found that the plaintiffs had made a strong showing that they were likely to prevail in proving that the '275 patent is invalid under the doctrine of non-statutory double patenting and, if valid, is unenforceable because of the equitable doctrine of prosecution laches. Id. at 289, 296-98. The request for a preliminary injunction was denied, however, because Biogen Idec MA and Genzyme had failed to make the required showing that they would be irreparably harmed if Columbia was not enjoined from terminating their licenses. Id. at 289, 298-301.

The fundamental facts concerning these cases as of August 13, 2004 are described in detail in the decision denying the motion for preliminary injunction, id. at 289-95, and will not be fully reiterated here. They are, in essence, as follows.

The Axel patents involve the use of recombinant DNA technology and a process called "co-transformation" to produce proteins in "host" cells which do not normally produce those proteins. Id. at 289-90. These proteins are used to make drugs that are important to human health. For example, Biogen Idec MA uses the technology it has licensed from Columbia to produce AVONEX (Interferon beta-la), the world's leading treatment for relapsing forms of multiple sclerosis. Id. at 291. AVONEX and the drugs manufactured by the other plaintiffs pursuant to their licenses with Columbia generate substantial revenues for the drug companies and substantial royalties for Columbia.

The three issued Axel patents, including the '275, each derive from application No. 06/124,513 (the "'513 application"), which was filed in 1980. Since 1980, Columbia has filed, and in some cases abandoned, a series of divisional and continuation applications. Id. at 291-93. Most significantly, for the purpose of these cases:

> On June 7, 1995, Columbia filed two more continuation applications, Nos. 08/484,136 (the "'136 application") and 08/477,159 (the "'159 application"). The June 7, 1995 filing date for the '136 and '159 applications is very significant. On December 8, 1994, Public Law No. 103-465, the Uruguay Round Agreements Act, was enacted. Among other things, this legislation provided that all patents that issue based on applications filed on or after June 8, 1995--6 months after the Act was signed into law--would expire twenty years from the date the application was filed. See 35 U.S.C. § 154(a)(2). The old rule was that patents expired seventeen years from the date of issuance. See 35 U.S.C. § 154 (1988). In order to grandfather in pending applications, the new law provided that all patents that issue based on applications filed before June 8, 1995 will last until either twenty years

> from the date the application was filed or seventeen years from the date the patent issues, whichever is later. See 35 U.S.C. § 154(c)(1)(A).
>
> The '159 application is still pending, now more than nine years after being filed. However, by virtue of the application being filed on June 7, 1995, if the '159 application results in a patent (a "'159 patent"), it will be effective for seventeen years. If the '159 application had been filed a day later, a '159 patent would either not now issue or would immediately be deemed expired because the twenty-year period after the 1980 filing of the original application from which it derives ended in 2000.
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> The '136 application ultimately matured into the '275 patent involved in this litigation. It was issued on September 24, 2000. Had the '136 application been filed one day later, the '275 patent too either would not have issued or would have been immediately deemed expired on February 25, 2000 because its application date relates back to its great-great-great-great-great-great-grandparent application, the 1980 '513 application. However, since the '136 application was, by one day, eligible for the seventeen years from issuance term, it will not expire until September 24, 2019--seventeen years after the date on which it was issued.

Id. at 292 (footnote omitted).

In connection with their request for preliminary injunction, the plaintiffs presented the declaration of Harvey F. Lodish on the issue of non-statutory double patenting. Id. at 296-97. Dr. Lodish is a professor at the Massachusetts Institute of Technology, and the lead author of an important, relevant textbook, Molecular Cell Biology. Id. at 297. Dr. Lodish explained in detail "why the three independent claims of the '275 patent that he analyze[d] 'are not patentably distinct over claims of the [earlier] '017 patent and are all invalid for obviousness type double patenting.'" Id.

(quoting Lodish Decl. ¶24). Based on his undisputed and compelling analysis, the court found that plaintiffs were likely to prevail in proving that the '275 patent is invalid. Id.

In addition, the court found that:

> In the instant case, the '275 patent was issued twenty-two years after the application from which it derives was filed. There were several delays in the prosecution of the application. Columbia has provided no evidence, or even argument, to explain why it took twenty-two years to obtain the '275 patent or to justify the delays in that process. The timing of its issuance strongly suggests that Columbia deliberately delayed obtaining a patent that it always intended to secure in order to make it effective just as the other Axel patents expired and thus increase its commercial value by maximizing the period in which the public would have to pay Columbia royalties for the use of the Axel patents.
>
> Accordingly, plaintiffs have made a strong showing that they are likely to prevail on the claim that, if valid, the '275 patent is unenforceable because of prosecution laches.

Id. at 298 (footnote omitted). As indicated earlier, however, because the moving plaintiffs failed to make the required showing of an imminent threat of irreparable harm, their motion for a preliminary injunction was denied. Id. at 298-301.

Also after a hearing on June 22, 2004, the court, on August 16, 2004, denied Columbia's motion for a stay of the multidistrict litigation pending the conclusion of Patent and Trademark Office (the "PTO") reexamination and reissuance proceedings concerning the '275 patent. In re Columbia University Patent Litigation, 330 F.Supp.2d 12 (D. Mass. 2004). In doing so, the court stated, in part, that:

> A stay would significantly harm the plaintiffs. While any stay is in effect, the drug companies' potential damages will mount. The uncertainty over whether they owe Columbia royalties on their products might create difficulties in pricing those products. It may also cause the drug companies to delay introduction of new products or needlessly invest money in efforts to design around an invalid patent. Such efforts are likely to be extremely costly in a highly regulated industry such as the one in which the drug companies compete because changes in their product designs or manufacturing processes may require regulatory approval.
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> Eliminating this uncertainty is the very reason that the plaintiffs brought these declaratory judgment actions. It is also the reason that Congress and the President created a declaratory judgment remedy. See 28 U.S.C. §2201.
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> A stay would also have the effect, if not the purpose, of causing delay in a case which involves, in part, the assertion that the '275 patent is unenforceable under the doctrine of prosecution laches because of the twenty-two year delay in prosecution that has already taken place. See Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., 277 F.3d 1361 (Fed. Cir. 2002); In re Bogese II, 303 F.3d 1362 (Fed. Cir. 2002). Now, over twenty-four years after he first filed the '513 application, John P. White, on behalf of Columbia, is telling the PTO that the patent should be re-issued because the issued claims are not broad enough. If the claims of the '275 patent are invalid as issued, the broader claims may be invalid as well. In denying the motion of Biogen and Genzyme to preliminarily enjoin termination of their license agreements, this court found that they have shown that they are likely to prevail in proving that if the '275 patent is valid, it is unenforceable because of prosecution laches. See Biogen Idec MA Inc., supra, 332 F.Supp.2d at 298. This finding militates against granting the complete stay of this case that Columbia seeks.

Id. at 17 (footnote omitted).

While the request for a complete stay was denied, the court substantially stayed what promised to be a prolonged period of

wide-ranging discovery in order to focus on an issue that it perceived had the potential to resolve this multidistrict litigation efficiently. More specifically:

> [A]t the June 22, 2004 hearing the court identified the contention that the '275 patent is invalid under the doctrine of non-statutory double patenting as one that should be able to be quickly developed and decided in 2004, either on a motion for summary judgment or at a trial to be conducted in December 2004. See Geneva Pharms., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003); Biogen Idec MA Inc., supra, 332 F.Supp.2d at 295. Therefore, the court established a schedule for the resolution of the non-statutory double patenting issue in 2004, and otherwise substantially stayed the remainder of this case to permit the parties to focus on that issue, which may, as a practical matter, end these cases. See June 23, 2004 Order (Docket No. 32).

Id. at 18.

On September 1, 2004, Columbia filed a covenant not to sue plaintiffs for infringement of the '275 patent as it now reads for any products made, used, or sold on or before September 1, 2004. Columbia then filed a motion to dismiss all of plaintiffs' declaratory judgment claims, asserting that no actual cases or controversies any longer existed and, therefore, the court lacked subject matter jurisdiction concerning them. Columbia subsequently informed Biogen Idec MA, Genzyme, Abbott and Johnson & Johnson that their licenses were still in effect because their failures to pay royalties on the '275 patent was not a breach of their licensing agreements.[2]

[2]Columbia has not deemed licenses to be in effect for Wyeth, Genetics Institute, Genetech, Amgen and Immunex because of issues

Plaintiffs opposed the motions to dismiss. Their oppositions relied primarily on the fact that Columbia's covenant not to sue covered only activities occurring before September 1, 2004. Several plaintiffs provided affidavits stating that they were engaged in research activity that potentially infringed the '275 patent and that they had taken concrete steps towards additional potentially infringing activity after September 1, 2004. Specifically, the plaintiffs stated that their ongoing research programs involved the co-transformation of Chinese Hamster Ovary cells, an activity that could potentially infringe the '275 patent. See e.g., Amgen and Immunex's Hu Decl. ¶¶4 and 5; Biogen's Prentice Decl. ¶¶ 2 and 3. As such activity was occurring after September 1, 2004, and was not covered by Columbia's covenant, plaintiffs argued that they were still at risk of being sued for infringement.

Plaintiffs also contended that the covenant not to sue did not extinguish the actual cases and controversies because the '159 application is based on the same specification as the '275 patent and, therefore, the claims that are now in the '275 patent might emerge in an eventual '159 patent. In addition, plaintiffs asserted that the fact that the covenant not to sue does not cover legally distinct but related entities, which they call "affiliates," contributes to the existence of enduring cases and controversies.

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that do not involve the validity or enforceability of the '275 patent.

They also argued that their claims for attorneys fees as "prevailing parties" under 35 U.S.C. §285 create actual cases and controversies.

At the October 6, 2004 hearing on the motion to dismiss, Columbia enlarged the scope of its covenant not to sue on the '275 patent. As memorialized in the Amended and Restated Covenant filed on October 12, 2004, Columbia has now agreed: 1) not to assert any claim against plaintiffs under the '275 patent as it currently reads and 2) not to assert the '275 patent as it currently reads against any plaintiff as a basis to recover royalties under such plaintiff's license agreement with Columbia. The current covenant covers "any and all methods, processes, and products made, used, offered for sale, sold, or imported by any plaintiff at any time[.]" In addition, it "covers all claims in the '275 patent as they currently read, and any claim in any reissued or reexamined version of the '275 patent that is the same as, or substantially identical to, any claim of the '275 patent as it currently reads."

Therefore, under the covenant not to sue, plaintiffs now have no potential liability for their current activities under the '275 patent or any other existing or potential Axel patent. Nor will they have any prospective liability under any reissued or reexamined '275 patent for any claim now in the '275 patent or any substantially identical claim.

The current covenant does not, however, cover any claim in any

reissued or reexamined '275 patent that is not the same as, or substantially identical to, any claim of the '275 patent as it now reads. The current covenant also does not cover any claims that may issue from the '159 application, even if such claims are the same as, or substantially identical to, claims in the '275 patent as it now reads. Finally, the covenant does not cover "affiliates" of plaintiffs that are not parties to these cases.

However, as discussed more fully below, it is unlikely that a '159 patent will issue with claims that are now in the '275 patent or substantially similar claims. The PTO has issued a final rejection of the proposed '159 patent due to obvious-type double patenting and recently reaffirmed that rejection. In any event, plaintiffs are not now incurring any potential liability to Columbia, and Columbia is not explicitly or implicitly threatening to sue any of them as a result of their current activities.

III. ANALYSIS

A. The Applicable Standards

The Declaratory Judgment Act, 28 U.S.C. §2201, provides in pertinent part that:

> In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought(emphasis added).

This means that a declaratory judgment may be issued only if there is a live case or controversy, as required by Article III of the

Constitution, at the time a court decides the case. See Spectronics Corporation v. H.B. Fuller Company, Inc., 940 F.2d 631, 635 (Fed. Cir. 1991). Moreover, "[s]imply because there is an actual controversy between the parties does not mean that the district court is required to exercise that jurisdiction." EMC Corporation v. Norand Corporation, 89 F.3d 807, 813 (Fed. Cir. 1996). Rather, even where an actual case or controversy exists, the court must make "'a reasoned judgment whether the investment of time and resources will be worthwhile.'" Id. (quoting Serco Servs. Co., L.P. v. Kelley Co., Inc., 51 F.3d 1037, 1039 (Fed. Cir. 1995)); see also Capo, Inc. v. Dioptics Medical Products, No. 04-1045, 2004 WL 2397342, at *3 (Fed. Cir. Oct. 25, 2004).

In the context of patents, the Declaratory Judgment Act recognizes the potential for abuse if patentees explicitly or implicitly threaten litigation without bringing suit in order to obtain a settlement or other commercial advantage from competitors faced with the "'in terrorem choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises.'" Id. at 814-15 (quoting Arrowhead Industrial Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 734-35 (Fed. Cir. 1988)).

> The purpose of the Act is to enable a person who is reasonably at legal risk because of an unresolved dispute, to obtain judicial resolution of that dispute without having to await the commencement of legal action by the other side. It accommodates the practical situation wherein the interests of one side to the

> dispute may be served by delay in taking legal action. However, the controversy must be actual, not hypothetical or of uncertain prospective occurrence. The requirement of actual controversy encompasses concepts such as ripeness, standing, and the prohibition against advisory judicial rulings . . .

BP Chemicals Ltd. v. Union Carbide Corp., 4 F.3d 975, 977 (Fed. Cir. 1993).

"In promulgating the Declaratory Judgment Act, Congress intended to prevent avoidable damages from being incurred by a person uncertain of his rights and threatened with damage by delayed adjudication." Minnesota Mining and Manufacturing Co. v. Norton Company, 929 F.2d 670, 673 (Fed. Cir. 1991). Therefore, in a patent case a plaintiff seeking a declaratory judgment generally must prove two essential elements to establish that an actual case or controversy exists.

> There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1058 (Fed. Cir. 1995). "'[T]he purpose of the two-part test is to determine whether the need for judicial attention is real and immediate' in which case the federal courts have jurisdiction, or whether it is 'prospective and uncertain of occurrence' in which case they do not." Id. (quoting BP Chemicals, 4 F.3d at 978).

In this multidistrict litigation, each of the plaintiff drug

companies is using a process to produce drugs which could constitute infringement of the '275 patent if it is valid and enforceable. Therefore, the second prong of the Super Sack test is satisfied.

However, Columbia's covenant not to sue any plaintiff on any "claims in the '275 patent as they currently read, and any claim in any reissued or reexamined patent that is the same as, or substantially identical to any claim of the '275 patent as it currently reads" means that plaintiffs do not now have the required reasonable apprehension that they will face an infringement suit and possibly be required to pay damages for any of their current activities. Id. The plaintiffs are not now "reasonably at legal risk because of an unresolved dispute." BP Chemicals, 4 F.3d at 977. Therefore, no case or controversy now exists in any of these actions. See Spectronics, 940 F.2d at 636-38.

This conclusion is not qualified by the fact that it is conceivable, although not likely, that claims now in the '275 patent could be included if a '159 patent is ever issued because the application for it is based on the specification that is in the '275 patent. Nor is the conclusion that these actions no longer present actual cases or controversies altered because plaintiffs allege not only that the '275 patent and the potential '159 patent are or would be invalid, but also that they are or would be unenforceable because of prosecution laches. See Intellectual

Property Development, Inc. v. TCI Cablevision of California, Inc., 248 F.3d 1333, 1342 n.9 (Fed. Cir. 2001). Moreover, even if actual cases or controversies were now deemed to exist, the court would exercise its discretion to dismiss the requests for declaratory judgment.

The reasons for these conclusions are as follows. "Although the requirement that the declaratory plaintiff be under a reasonable apprehension of suit does not require that the patentee be known to be poised on the courthouse steps," defendant's actions must create an objectively reasonable apprehension of litigation on the part of a declaratory judgment plaintiff. Philips Plastics Corporation v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1054 (Fed. Cir. 1995). "The Declaratory Judgment Act was intended to protect threatened parties, not to drag a non-threatening patentee into court." Shell Oil Company v. Amoco Corporation, 970 F.2d 885, 889 (Fed. Cir. 1992).

Covenants not to sue made after the commencement of a declaratory judgment action may eliminate a plaintiff's reasonable apprehension of infringement litigation and, therefore, the required actual case or controversy. See Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999); Super Sack, 57 F.3d at 1060. A comparison of the instant cases with Spectronics demonstrates that actual cases or controversies no longer exist in the instant actions.

In Spectronics, 940 F.2d at 633, the plaintiff sought a declaration "of invalidity or non-infringement of the claims" of United States Patent No. 4,758,366 (the "'366 patent"). During the pendency of the action, defendant H.B. Fuller Company, Inc. ("Fuller") filed an application in the PTO seeking the reissuance of the '366 patent. Subsequently, Fuller filed a covenant not to sue Spectronics for infringement of the '366 patent claims. Id. at 633. Fuller's covenant did not estop it from charging Spectronics with infringement of new claims that might result from its reissue application. Id.

The Federal Circuit found that Fuller's covenant eliminated any case or controversy between Fuller and Spectronics because "in view of the statement of non liability, Fuller is forever estopped from asserting the '366 patent claims against Spectronics. Having requested a declaration of non-infringement of the '366 patent claims, Spectronics for all practical purposes has won the case pleaded in its complaint." Id. at 636. The Federal Circuit also held that the mere possibility of a reissuance of the '366 patent with new claims was insufficient to create an actual case or controversy. Id. at 636-38.

Columbia's current covenant similarly estops it from ever suing plaintiffs on the claims of the '275 patent as it now reads, even if they are reissued. If the '275 patent is reissued with new or amended claims, they will be "enforceable only from the date of

reissue and . . . [t]he specific things made before the date of the reissue, which infringe the new reissue claims, are absolutely free of the reissued patent and may be used or sold after the date of reissue without regard to the patent." Id. at 637 (internal quotation and citation omitted).

Therefore, plaintiffs' present rights are clear, and there is no risk that they will be required to pay Columbia damages for their current activities or products even if the '275 patent is reissued with new or amended claims. Accordingly, the reasons for the Declaratory Judgment Act no longer pertain to this case. See Minnesota Mining, 929 F.2d at 673; Arrowhead, 846 F.2d at 734-35. More significantly, no actual cases or controversies any longer exist. See Spectronics, 940 F.2d at 636-37.

In their effort to distinguish Spectronics, plaintiffs rely primarily on two contentions. Neither is persuasive.

In Spectronics, the Federal Circuit stated, Spectronics "has no cause for concern that it can be held liable for practicing the invention claimed in the '366 patent." Id. at 638. Plaintiffs argue that, in contrast, they could arguably be held liable prospectively for practicing inventions claimed in the '275 patent if the claims of '275 patent reemerge in a patent that issues from the '159 application. Therefore, they contend that the protection provided by Columbia's covenant is insufficient to extinguish the actual cases or controversies between the parties.

However, in GAF Building Materials v. Elk Corporation of Dallas, 90 F.3d 479, 482 (Fed. Cir. 1996), the Federal Circuit held that "a threat [of suit] is not sufficient to create a case or controversy unless it is made with respect to a patent that has issued before a complaint is filed." As authority for this holding, the Federal Circuit quoted its earlier statement in Spectronics, 940 F.2d at 636, that "the existence of issued patent claims, presently enforceable against [the declaratory judgment plaintiff], are a requisite to litigation of a declaratory judgment action." See also Muskegon Piston Ring Co. v. Olsen, 307 F.2d 85, 89 (6th Cir. 1962) (If there is no issued patent, "no controversy under the patent laws exists, upon which [the accused infringer] can bring an action for a declaratory judgment in the federal court."). In Spectronics, the Federal Circuit found that there was not the required objectively reasonable apprehension about a future suit because "'the ultimate fate and legal effect of [a] pending patent application is inherently uncertain'" and there was "no guarantee that the reissue patent will eventually issue." Id. at 636 (quoting State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1236 (Fed. Cir. 1985)).

In the instant case, no '159 patent has issued. Pursuant to the unqualified holdings of Spectronics and GAF, this may be the end of the inquiry with regard to the implications of the possible '159 patent.

Moreover, the issuance of a '159 patent with claims that are now in the '275 patent is not only uncertain, it is unlikely. As described earlier, in deciding the motion for preliminary injunction, this court found that "the plaintiffs have made a strong showing that they are likely to prove that the '275 patent is invalid under the doctrine of non-statutory double patenting." Biogen Idec MA, 332 F. Supp.2d at 296. The decisions of the PTO concerning the '159 application are consistent with this court's preliminary evaluation of plaintiffs' double patenting claims. On January 1, 2004, the PTO issued a final rejection of the '159 patent due to obvious-type double patenting. On September 8, 2004, the PTO issued an advisory action stating its belief that the final rejection was appropriate. Although Columbia is continuing its quest to have a '159 patent issued, this court finds that it is unlikely that any such patent will issue with any claims now in the '275 patent or any substantially similar claims. Accordingly, even assuming that despite the unqualified holdings in GAF and Spectronics the required reasonable apprehension of suit could properly be found in some cases prior to the issuance of a patent, these are not such cases.

Plaintiffs also seek to distinguish Spectronics on the ground that in Spectronics, 940 F.2d at 636, the declaratory judgment plaintiff was asserting non-infringement and invalidity, but in this case the plaintiffs make similar assertions and also contend

that the '275 patent is unenforceable because of prosecution laches. It is true that after finding that it was "inherently uncertain" whether the '366 patent would reissue, the Federal Circuit wrote:

> Furthermore, even if Spectronics had an objectively reasonable apprehension about a future suit based upon the reissue patent, we would be compelled to affirm the District Court's dismissal because Spectronics cannot demonstrate that its present activity is potentially infringing on any patent claims, since it is immune to suit under the '366 patent, and no reissue patent claims yet exist by which infringement vel non can be measured.

Id. Plaintiffs assert that: Spectronics does not address an argument based on unenforceability; prosecution laches does not require consideration of specific claims; and, therefore, this case is materially different than Spectronics.

This contention is not, however, consistent with the sole Federal Circuit case which has addressed it or the principles on which the doctrine of prosecution laches is founded. Intellectual Property, 248 F.3d at 1342 n.9, involved assertions that the patent at issue was not infringed, was invalid, and was unenforceable. Addressing the requirement of a reasonable apprehension of being sued, the Federal Circuit stated that "[i]t is of no consequence to the case at issue that Super Sack concerned a declaratory counterclaim for noninfringement and invalidity while TCI-California counterclaimed for declaratory judgment on the issues of noninfringement, invalidity, and unenforceability." Id. (emphasis added).

Prosecution laches is a basis for finding that patent claims are unenforceable rather than invalid. See In re Bogese II, 303 F.3d at 1367; Reiffen v. Microsoft Corp., 270 F. Supp. 2d 1132, 1155 (N.D. Cal. 2003). Addressing whether there was an actual case or controversy regarding assertions of noninfringement and invalidity in Spectronics, the Federal Circuit wrote:

> There are sensible reasons why the existence of issued patent claims, presently enforceable against Spectronics are a requisite to litigation of a declaratory judgment action. The claims of the patent are the subject matter of the suit.

Spectronics, 940 F.2d at 636. The claims of the patent are also the subject matter of an action seeking declaratory judgment of unenforceability based on prosecution laches.

The equitable defense of prosecution laches not only addresses the possibility that the length of a patent claim will be unfairly extended. "[T]he prosecution laches defense also responds to concerns that inventors will file narrow claims, await intervening developments, and then file broader claims to cover those developments." Chiron Corporation v. Genentech, Inc., 268 F. Supp. 2d 1139, 1142 (E. D. Cal. 2002). This concern is implicated in the instant cases. In the pending PTO proceedings Columbia is "telling the PTO that the ['275] patent should be reissued because the issued claims are not broad enough." In re Columbia University Patent Litigation, 330 F.Supp.2d at 17. Columbia may be making the same argument in its effort to have '159 patent issued.

In Symbol Technology, 277 F.3d at 1363, the Federal Circuit wrote in recognizing the doctrine of prosecution laches that "[t]he sole issue on appeal is whether, as a matter of law, the equitable doctrine of laches may be applied to bar the enforcement of patent claims that issued after an unreasonable and unexplained delay in prosecution even though the applicant complied with pertinent statutes and rules" (emphasis added). "While the test of reasonableness is objective, the inquiry remains fact-intensive." Reiffen, 270 F.Supp.2d at 1154. Unless and until actual claims are issued, it is not possible to assess whether the explanation for any delay in prosecuting them was reasonable. Thus, "the existence of issued patent claims" should be deemed to be "a requisite to litigation of a declaratory judgment action" alleging unenforceability due to prosecution laches as well as infringement. Spectronics, 940 F.2d at 636. This reasoning is consistent with the Federal Circuit's holding that the fact that Intellectual Property involved a claim of unenforceability, as well as claims of non-infringement and invalidity, was of "no consequence." 248 F.3d at 1342 n.9.[3]

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[3]The court recognizes that in Kosower v. Gutowitz, 2001 WL 1488440, *6 n.6 (S.D.N.Y. 2001), it was held that an actual case or controversy existed in a dispute concerning, among other things, inventorship in a pending PTO application. The court in Kosower based that decision on 35 U.S.C. §116, which expressly provides for correction of a pending application. Id. It noted that "the plaintiff seeks to correct a pending application and does not seek an adjudication of the validity or infringement of the yet-to-be-issued patent." Id. n.6. The court found that this

In deciding the motion for a preliminary injunction this court found that the plaintiffs were likely to prove that the '275 patent is unenforceable under the doctrine of prosecution laches as well as invalid for double patenting. Biogen Idec MA, 332 F.Supp.2d at 297. In connection with the motion for preliminary injunction, Columbia "provided no evidence, or even argument, to explain why it took twenty-two years to obtain the '275 patent or to justify the delays in that process." Id. at 298. Unless the record were materially altered, the court's evaluation concerning the '275 patent claims would also apply to the same or substantially similar claims in any '159 patent that might issue.

"[I]n In re Bogese II, 303 F.3d at 1367-68, the Federal Circuit held that the PTO may refuse to grant a patent because of prosecution laches." In re Columbia University Patent Litigation, 330 F.Supp.2d 12, 16 (D. Mass. 2004). Indeed, "the PTO's authority to sanction undue delay is even broader than the authority of a district court to hold a patent unenforceable." In re Bogese II, 303 F.3d at 1367. Therefore, if Columbia cannot explain and justify the delay in prosecuting the claims in the '275 patent, the doctrine of prosecution laches, as well as the doctrine of double

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distinguished Kosower from GAF. Id. It did not consider the holding in Intellectual Property, 248 F.3d at 1342 n.9.

As the instant cases do not implicate 35 U.S.C. §116, they are distinguishable from Kosower. To the extent, if any, that this distinction may be immaterial, this court respectfully disagrees with the reasoning of Kosower.

patenting, makes it unlikely that the same or substantially similar claims will be included in any '159 patent that may issue. See Biogen Idec, 332 F.Supp.2d at 299.

In these circumstances, plaintiffs do not have a reasonable apprehension of suit on the claims now in the '275 patent which theoretically could also be included in a '159 patent. They are not now "reasonably at legal risk because of any unresolved dispute." BP Chemicals, 4 F.3d at 976. Rather, "the controversy . . . is hypothetical [and] of uncertain prospective occurrence." Id. Thus, there are not actual cases or controversies for declaratory judgment now before the court. See Super Sack, 57 F.3d at 1058.

Moreover, even if actual cases or controversies now existed, this court would exercise its discretion to dismiss the requests for declaratory judgment. See EMC, 89 F.3d at 813-15. As a result of the covenant not to sue, the plaintiff drug companies have no potential liability for their current activities. They are not now threatened with suit. Nor is Columbia now attempting to use the '275 patent to obtain some commercial advantage without filing suit. Therefore, these cases do not now involve the type of situation that the Declaratory Judgment Act was intended to address. See EMC, 89 F.3d at 814-15; Arrowhead, 846 F.2d at 734-35.

For the reasons described earlier, it is unlikely that a '159 patent will issue, particularly with the claims that are now in the '275 patent or substantially similar claims. Therefore, a

declaratory judgment would be based solely on hypothetical facts and would, in effect, be advisory. Issuing such a judgment is not permissible or appropriate. See BP Chemicals, 4 F.3d at 977; compare Minnesota Mining, 929 F.2d at 674-75 (court abused discretion in dismissing declaratory judgment action for noninfringement when the pending interference proceeding could not "decide (or is not likely to moot) the infringement issues and when the declaratory judgment plaintiff will likely suffer significant ongoing harm during any delay.").

It would, however, take a great deal of this court's limited resources to decide the issues that plaintiffs present. This is multidistrict litigation, which this court has been prepared to give high priority. As described earlier, shortly after being assigned these cases, in June 2004, the court identified the issue of non-statutory double patenting as one that could resolve them quickly, and possibly eliminate very expensive uncertainty for the plaintiff drug companies and the public that they serve. Therefore, the court "established a schedule for resolving within five months the merits of plaintiffs' non-statutory double patenting challenge to the '275 patent on a motion for summary judgment or at trial." Biogen Idec MA, 332 F. Supp. at 300. This schedule included hearing and deciding a motion for summary judgment in November 2004. If that motion was denied, a non-jury trial would have been conducted in December 2004, and the court would have been required to issue

a decision. In essence, these cases would have taken virtually all of this court's time for several months.

This court is also assigned several hundred other civil and criminal cases. Many of the criminal cases involve defendants who are detained pending trials which would inevitably be delayed for the period that the court was consumed with these cases.

This court was fully prepared to devote the time and resources necessary to attempt to resolve these cases expeditiously when there was a live and definite controversy between the parties. However, the covenant not to sue has eliminated the uncertainty over whether plaintiffs owe Columbia royalties for their present activities and products, and there is not now an enforceable patent that they must plan around. Compare In re Columbia Patent Litigation, 330 F.Supp2d at 17 (denying stay). Plaintiffs have, "for all practical purposes . . . won the case[s] pleaded in [their] complaint[s]." Spectronics, 940 F.2d at 636.[4]

In these circumstances, the investment of the judicial time and resources necessary to decide plaintiffs' declaratory judgment claims would not be worthwhile. See EMC, 89 F.3d at 814. Here, "'the normal principle that federal courts should adjudicate claims within their jurisdiction yields to consideration of practicality

[4]If the declaratory judgment claims were not now being dismissed, the covenant not to sue on the '275 patent would give Columbia a strong new argument in support of a renewed motion to stay.

and wise judicial administration.'" Id. (quoting Wilton v. Seven Falls Co., 515 U.S. 277, 288 (1995)). To the extent, if any, that this is a discretionary matter, it is most appropriate to dismiss the requests for declaratory judgment rather than devote scarce judicial resources to deciding hypothetical issues in anticipation of an actual dispute that is not likely to occur.

Plaintiffs make three other arguments in their effort to persuade the court that actual cases or controversies exist. Each is without merit.

Some of the plaintiffs contend that an actual case or controversy exists because Columbia's covenant not to sue does not cover the independent legal entities they call "affiliates." Columbia has not, however, implicitly or explicitly threatened to sue those entities. More significantly, the "affiliates" are not parties to these cases. In Intellectual Property, 248 F.3d at 1341-42, the Federal Circuit stated that "[a] suit filed against a different party, even if TCI-California could potentially be required to indemnify that party, is not a suit that TCI-California itself faces." Therefore, the Federal Circuit held that no actual case or controversy concerning TCI-California existed and the case was properly dismissed. Id. Similarly, conceivable claims against "affiliates" of the plaintiffs in these cases are insufficient to generate the required actual cases or controversies that have been extinguished by Columbia's covenant not to sue the plaintiffs on

the claims of the '275 patent.

Plaintiffs also contend that their demands for attorneys fees pursuant to 35 U.S.C. §285 create actual cases and controversies. Section 285 provides that "[t]he court in exceptional cases may award reasonable attorneys fees to the prevailing party." In interpreting the term "prevailing party" in another statute providing for fee-shifting, the Supreme Court has held that:

> A defendant's voluntary change in conduct, although perhaps accomplishing what the plaintiff sought to achieve by the lawsuit, lacks the necessary judicial imprimatur on the change. Our precedents thus counsel against holding that the term "prevailing party" authorizes an award of attorney's fees without a corresponding alteration in the legal relationship of the parties.

Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't of Health and Human Resources, 532 U.S. 598, 605 (2001). The Federal Circuit has noted that "[t]he Supreme Court has interpreted the phrase 'prevailing party' consistently in all federal fee-shifting statutes." Former Employees of Motorola Ceramic Products v. United States, 336 F.3d 1360, 1364 (Fed. Cir. 2003). Thus, the Federal Circuit has held that §285 requires that "to be a prevailing party, one must receive at least some relief on the merits, which alters . . . the legal relationships of the parties." Inland Steel Company v. LTV Steel Company, 364 F.3d 1318, 1320 (Fed. Cir. 2004).

While Columbia's covenant not to sue is a form of voluntary conduct that accomplishes the major part of what the plaintiffs sought to achieve in these lawsuits, they have received no relief

from the court on the merits of their claims. They are, therefore, not prevailing parties for the purposes of §285. Id. Thus, their claims for attorneys fees do not create actual cases or controversies.

Finally, at the October 6, 2004 hearing Biogen Idec MA and Genzyme briefly argued that actual cases and controversies are created by their obligation to pay an annual $30,000 fee to Columbia to maintain their reinstated licenses. Oct. 6, 2004 Tr. at 40-41. Biogen Idec MA and Genzyme neither practice nor intend to practice the sole issued Axel patent other than the '275 patent, U.S. Patent No. 5,149,636. See Biogen Idec MA, 332 F. Supp. 2d at 293. They are unlikely to resume paying the annual license fee in view of their manifest intent to challenge the validity and enforceability of any '159 patent that may issue, and Columbia's duty to license to them any '159 patent at a reasonable rate if they lose that challenge. Id. at 291, 300. If Biogen Idec MA and Genzyme pay the annual license fee, any possible case or controversy may be extinguished. See Gen-Probe Incorporated v. Vysis, Inc., 359 F.3d 1376 (Fed. Cir. 2004). Moreover, their counsel has stated that, "we wouldn't be here [in litigation] today if we were fighting over the $30,000." Oct. 6, 2004 Tr. at 41.

Thus, plaintiffs evidently do not intend to pay the license fee in any event and would not litigate whether they have a duty to do so if it were the sole issue in dispute. Therefore, the question

of the annual license fee does not create actual cases or controversies because the need for judicial attention is not real and immediate. See Super Sack, 57 F.3d at 1058; BP Chemicals, 4 F.3d at 978. If it did, the court would exercise its discretion to dismiss the requests for declaratory judgment concerning the license fee because at this point the investment of judicial time and resources necessary to decide them would not be worthwhile. See EMC, 89 F.3d at 813.

IV. ORDER

In view of the foregoing, it is hereby ORDERED that:

1. Columbia University's Emergency Motion to Dismiss for Lack of Subject Matter Jurisdiction (Docket No. 86) is ALLOWED.

2. Counsel for the parties shall confer and, by December 6, 2004, file a report:

a. Stating whether they agree that all of the claims listed in the attached Proposed Order submitted by Columbia should be dismissed pursuant to this Memorandum and Order.

b. Identifying each case that should be completely dismissed pursuant to this Memorandum and Order.

c. Identifying the remaining cases and counts.

d. Informing the court whether it would now be worthwhile for the parties to attempt to settle the remaining cases and claims and, if so, propose a schedule for doing so.

e. Informing the court whether a stay concerning any or all of the remaining cases and claims should be entered.

f. Informing the court of the schedule they recommend for resolving the remaining cases and claims if a stay is not entered.

/s/ MARK L. WOLF
UNITED STATES DISTRICT COURT